DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAY - 7 1999

The Honorable Henry A. Waxman
Committee on Commerce
House of Representatives
Washington, D.C. 20515

Dear Mr. Waxman:

Thank you for your letter of March 25, 1999, co-signed by Representatives Dingell, Klink, and Brown, on the subject of pharmaceutical sales over the Internet. We appreciate and welcome your interest in this rapidly emerging issue, as the Food and Drug Administration (FDA or the Agency), other Federal agencies and State entities work to define and respond to the issues presented by this phenomenon. Each question in your March 25 letter is restated below (in bold type), followed by FDA's response.

(1) What agency or department (at either the state or federal level) does FDA believe is the primary regulator of Internet pharmacies? For this question, please also identify and describe the roles of the other state/federal agencies that may make up this structure.

We are not aware that any government agency is the "primary regulator" of Internet pharmacies. FDA does not generally regulate pharmacies. FDA regulates products and certain activities related to those products, particularly when carried out by or on behalf of a manufacturer, packer, or distributor. Under the Federal Food, Drug, and Cosmetic (FD&C) Act, FDA can take action against illegal promotion (labeling and advertising) of a prescription drug; illegal labeling of an over-the-counter drug; the importation, sale, or distribution of an adulterated or misbranded drug; the importation, sale, or distribution of an unapproved new drug; and the sale or dispensing of a prescription drug without a valid prescription. The States, however, have traditionally regulated the dispensing of drugs. Internet sites that carry out any of the above illegal acts are subject to regulatory action by FDA or the appropriate State agency.

Other aspects of Internet drug sales are subject to enforcement activities by other Federal agencies. The Federal Trade Commission (FTC) has responsibility for the advertising of non-prescription drugs, while the Drug Enforcement Administration (DEA) regulates controlled substances. The Department of Justice enforces civil consumer protection statutes and criminal provisions. Finally, the U.S. Postal Service and the U.S. Customs Service enforce statutes and regulations governing the importation and domestic mailing of drugs.

In an effort to enhance interagency cooperation, FDA facilitated a meeting with a number of federal agencies and representatives of state regulatory bodies on April 26, 1999. Meeting participants discussed their roles in regulating Internet sales of drugs in an effort to advance interagency cooperation and bring clarity to issues relating to jurisdiction. Participants included the FTC, DEA, Federal Bureau of Investigation, Customs Bureau, Postal Service and State pharmacy regulators.

(2) What specific activities or functions does FDA believe it is responsible for with regard to regulating Internet pharmacies? Please describe both the precise activities now conducted by FDA, and the number of full-time equivalents (FTEs) dedicated to all identified efforts. Does FDA believe it has enough resources to conduct the activities it presently feels are under its jurisdiction in this regard? If, not, what additional resources does FDA require?

As noted in the above response, FDA does not generally regulate pharmacies. FDA regulates products and certain activities related to those products, particularly when carried out by or on behalf of a manufacturer, packer, or distributor. The States, however, have traditionally regulated the dispensing of drugs.

The Office of Compliance in FDA's Center for Drug Evaluation and Research (CDER) reviews Web sites that consumers, industry or health professionals report as appearing to be violative. CDER has taken a number of actions, such as sending Warning Letters to firms using the Internet to illegally promote the sale of unapproved new drugs and issuing Import Alerts on illegal foreign products sold on-line. FDA has also contacted Web site managers and asked for their voluntary cooperation in removing offensive sites. Warning Letters to offshore

pharmacies are shared with the firm's home government, from whom we request cooperation. Additionally, CDER's Division of Drug Marketing, Advertising and Communications has taken steps against Internet promotion that violates the FD&C Act, for example, by making unsubstantiated claims for drugs or misrepresentations, or by a lack of fair balance in describing risks versus benefits.

FDA possesses limited authority over international sales and limited resources to control domestic and international sales. Clearly, oversight of the variety of public health related activities that can occur on the Internet requires the attention not only of FDA and other Federal agencies, but also State licensing and regulatory boards, the pharmaceutical industry and medical professional organizations.

The Agency is in the process of developing draft guidance for industry to provide clarification on use of the Internet for promoting regulated products.

FDA does not have any employees that are dedicated full-time to monitoring Internet sites that sell drugs or undertaking regulatory activities involving such sites. Assignments to regulatory personnel are made as information becomes available indicating that violations of the FD&C Act or FDA regulations may have occurred. Similarly, while some individuals with policy-making duties are currently spending substantial amounts of time on Internet drug sales issues, these also are not full-time assignments.

FDA has established an internal working group to explore other areas relating to Internet sales where the Agency's regulatory authority may be needed to protect the public health. Once this working group has made further progress and reported on its work, FDA then will be able to recommend to you what additional resources, if any, may be needed from Congress to address this area. We would also note that the assignment of personnel to Internet related issues may change as a result of the working group's efforts.

(3) Does FDA believe that existing laws and regulations, or the present state/federal regulatory structure adequately regulate online pharmacy operations? If not, what are the discrepancies, and what changes, if any, does FDA believe must be made?

As noted above, FDA's internal working group is currently exploring avenues available to the Agency under our existing authority to address Internet sales as well as additional authorities that may be needed. Once the working group makes recommendations on this matter, FDA will be able to indicate what legislative changes may be needed to provide additional authorities. We expect to gain additional perspective on this issue as we review the results of the April 26, 1999 meeting with Federal and State agencies.

Because pharmacies are generally regulated at the State level, the question of whether existing laws and regulations are sufficient to protect the public health from risks associated with Internet pharmacies should also be addressed to those State organizations responsible for the regulation of pharmacies.

(4) Please describe FDA's knowledge regarding the differences between existing online pharmacies. For example, some reports suggest that most online pharmacies only fill prescriptions. Other reports, however, have suggested that some actually provide for a doctor consultation (for example, a quick questionnaire is submitted over the Internet, it is reviewed, and then the prescription is then approved and sent directly to the patient without a doctor ever seeing the patient). How prevalent is this latter operation? Do any trends appear in comparing one form of online pharmacy with another?

As FDA has more closely examined Internet sales of drugs over the past few months, we are struck by the diversity of Internet sites and the multi-faceted nature of the issues that are presented. Not only are questions raised about the authenticity of some pharmaceutical products sold on-line at certain Internet sites, but the legitimacy of some prescribing activity is also at issue. Because these are electronic transactions, the participants may be widely dispersed geographically and may well never meet. A consumer in one state, for instance, using a Web site emanating from a

computer in another state, may order a drug dispensed from a third state, using a prescription from a doctor in a fourth state.

This geographic diffusion and other unique characteristics of the Internet present regulators with novel challenges. In the example above, if one or more participants in the transaction are located outside of the United States, the task of regulating this activity is further complicated. Similarly, the fact that Web site operators may easily move the location of their sites makes enforcement all the more difficult.

Additionally, as regulators consider new enforcement strategies, a careful line must be drawn between unsafe or illegal practices over the Internet and legitimate communication and commerce which is increasingly utilizing this new medium. Examples of valid prescribing and dispensing activities using the Internet are 1) the use by patients of Web sites sponsored by well-established pharmacies to order refills of existing prescriptions, and 2) the use by physicians of electronic means to transmit prescriptions to pharmacies for patients they have properly evaluated.

FDA's primary concern about Internet sales is based on the long-standing principle that the selection of specific drug products or treatment regimens for a particular patient should be made with the advice of a licensed physician familiar with the patient's current health status and past medical history. FDA is greatly concerned about situations where the customary physician-patient relationship does not exist. In these situations, the prescriber must largely rely on the patient to practice self-diagnosis, which multiplies the risk of negative outcomes such as harmful drug interactions, allergic reactions, contraindications, or improper dosing. We do not, however, know how prevalent this type of operation is or if there are identifiable trends as to the prevalence of one type of online pharmacy versus another. We are not aware of any reliable estimates of the number of Internet sites that sell drugs, as new sites appear on the Internet every day, just as others disappear.

(5) What is FDA's understanding of how these firms deal with issues such as medical records, privacy/protection, the selling of controlled substances, or drug interactions? How serious are these issues and what shortcomings, if any, do

online pharmacies have with regard to these issues? Does FDA have any knowledge of how online pharmacies prevent unqualified persons from receiving prescriptions? Are online pharmacies more susceptible to fraud or deception? If so, please explain how?

FDA is not in a position to say whether on-line pharmacies have shortcomings in these areas. Issues pertaining to medical records and privacy protection are generally regulated by the States. In addition, the regulation of controlled substances is handled by the DEA.

While pharmacies are not required to report instances of adverse events or drug interactions, they are encouraged to submit such reports to FDA's MEDWATCH system. FDA maintains a link to MEDWATCH on our Internet site at www.fda.gov/medwatch. We take the issue of drug interactions and adverse reactions very seriously, however, we are not aware that these problems are more prevalent at pharmacies utilizing the Internet.

As to the question of how online pharmacies prevent unqualified persons from receiving prescriptions, FDA recognizes that various on-line pharmacies have different policies and procedures relating to this issue. Clearly, many on-line pharmacies do require valid prescriptions, but FDA is very concerned that some pharmacies do not. At this time, we have no information suggesting that on-line pharmacies are more susceptible to fraud or deception than other pharmacies. Susceptibility to fraud is increased at any pharmacy that takes orders without the customer physically present at the establishment or which dispenses medications through the mail rather than in person.

(6) Finally, what quality issues does FDA believe relate to the methods used to ship online pharmaceutical products, and does FDA believe it has jurisdiction in this area?

Standards enforced by FDA apply to all drugs sold in commerce in the United States, regardless of whether the order is placed in person, online or by the mail. Products that fail to meet quality standards would be adulterated or misbranded under the FD&C Act and subject to regulatory action by FDA.

We very much appreciate having your thoughts and knowing of your concerns regarding the sale of drugs over the Internet. We hope this information is useful to you and we look forward to working with you and your colleagues to address this important public health issue. A similar letter is being sent to your cosigners.

Sincerely,

Melinda K. Plaisier
Interim Associate Commissioner
for Legislative Affairs

cc: The Honorable Tom Bliley
Chairman
Committee on Commerce

The Honorable Michael Bilirakis
Chairman
Subcommittee on Health and Environment
Committee on Commerce

The Honorable Fred Upton
Chairman
Subcommittee on Oversight and Investigations
Committee on Commerce